

## MEDICAL DEVICE EXEMPTIONS

Below is a breakdown of 510(k) and Good Manufacturing Practice (GMP) exemptions for Class I devices compiled from Title 21 Code of Federal Regulations (CFR). The Food, Drug and Cosmetic Act under section 513(d)(2)(A) authorizes FDA to exempt certain generic types of class I devices from the premarket notification 510(k) requirement. FDA has exempted nearly 450 generic types of class I devices from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994 and January 16, 1996. Some 510(k) exemptions are with certain limitations and are noted below. **It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR xxx.9, where xxx refers to Parts 862-892.**

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, these manufacturers are required to register their establishment by submitting Form FDA 2891, "Initial Registration of Device Establishment," and list the generic category or classification name of the device by submitting Form FDA 2892, "Device Listing."

**IMPORTANT NOTE:** **Only** the class I devices with an asterisk (\*) below are also exempted from the GMP regulation, **except** for general requirements concerning records (820.180) and complaint files (820.198), *if the device is not labeled or otherwise represented as sterile.*

### PART 862 CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

862.1190	Copper test system
862.1210	Creatine test system
862.1255	2,3-Diphosphoglyceric acid test system
862.1290	Fatty acids test system
862.1305	Formiminoglutamic acid (FIGLU) test system
862.1320	Gastric acidity test system
862.1365	Glutathione test system
862.1380	Hydroxybutyric dehydrogenase test system
862.1420	Isocitric dehydrogenase test system
862.1470	Lipid (total) test system
862.1490	Lysozyme (muramidase) test system
862.1515	Nitrogen (amino-nitrogen) test system
862.1565	6-Phosphogluconate dehydrogenase test system
862.1575	Phospholipid test system
862.1640	Protein-bound iodine test system
862.1670	Sorbitol dehydrogenase test system
862.1720	Triose phosphate isomerase test system
862.1815	Vitamin E test system
862.2050 *	General purpose laboratory equipment labeled or promoted for a specific medical use
862.2100	Calculator/ data processing module for clinical use
862.2230	Chromatographic separation material for clinical use.
862.3750	Quinine test system
862.3850	Sulfonamide test system

## **PART 864 HEMATOLOGY AND PATHOLOGY DEVICES**

864.1850	*	Dye and chemical solution stains
864.2220		Synthetic cell and tissue culture media and components
864.2240	*	Cell and tissue culture supplies and equipment
864.2260		Chromosome culture kit
864.2360		Mycoplasma detection media and components
864.2800		Animal and human sera
864.2875		Balanced salt solutions or formulations
864.3010	*	Tissue processing equipment
864.3250		Specimen transport and storage container ( <b>non-OTC</b> )
864.3300		Cytocentrifuge
864.3400		Device for sealing microsections
864.3600	*	Microscopes and accessories
864.3800		Automated slide stainer
864.3875		Automated tissue processor
864.4010	*	General purpose reagent
864.4400		Enzyme preparations
864.5350		Microsedimentation centrifuge
864.5800		Automated sedimentation rate device
864.5850		Automated slide spinner
864.6150		Capillary blood collection ( <b>non-OTC</b> )
864.6160		Manual blood cell counting device
864.6600		Osmotic fragility test
864.6700		Erythrocyte sedimentation rate test
864.7660		Leukocyte alkaline phosphatase test
864.7675		Leukocyte peroxidase test
864.7900		Thromboplastin generation test
864.8200		Blood cell diluent
864.8500		Lymphocyte separation medium
864.8540		Red cell lysing reagent

## **PART 866 IMMUNOLOGY AND MICROBIOLOGY DEVICES**

866.2050		Staphylococcal typing bacteriophage
866.2120	*	Anaerobic chamber
866.2160		Coagulase plasma.
866.2170		Automated colony counter
866.2180	*	Manual colony counter
866.2300		Multipurpose culture medium
866.2320		Differential culture medium
866.2330		Enriched culture medium
866.2350		Microbiological assay culture medium
866.2360		Selective culture medium
866.2440	*	Automated medium dispensing and stacking device

866.2450	Supplement for culture media
866.2480	Quality control kit for culture media
866.2500	Microliter diluting and dispensing device
866.2540 *	Microbiological incubator
866.2560	Microbial growth monitor
866.2580	Gas-generating device
866.2600 *	Wood's fluorescent lamp
866.3010	Acinetobacter calcoaceticus serological reagents
866.3020	Adenovirus serological reagents
866.3035	Arizona spp. serological reagents
866.3065	Bordetella spp. serological reagents
866.3125	Citrobacter spp. serological reagents
866.3205	Echovirus serological reagents
866.3250	Erysipelothrix rhusiopathiae serological reagents
866.3255	Escherichia coli serological reagents
866.3270	Flavobacterium spp. serological reagents
866.3330	Influenza virus serological reagents
866.3340	Klebsiella spp. serological reagents
866.3400	Parainfluenza virus serological reagents
866.3410	Proteus spp. (Weil-Felix) serological reagents
866.3470	Reovirus serological reagents
866.3490	Rhinovirus serological reagents
866.3520	Rubeola (measles) virus serological reagents
866.3630	Serratia spp. serological reagents
866.3700	Staphylococcus aureus serological reagents
866.3720	Streptococcus spp. exoenzyme reagents
866.4100	Complement reagent
866.4500	Immunoelectrophoresis equipment
866.4520	Immunofluorometer equipment
866.4540	Immunonephelometer equipment
866.4600	Ouchterlony agar plate
866.4800	Radial immunodiffusion plate
866.4830	Rocket immunoelectrophoresis equipment
866.4900	Support gel
866.5170	Breast milk immunological test system
866.5220	Cohn fraction II immunological test system
866.5230	Colostrum immunological test system
866.5360	Cohn fraction IV immunological test system
866.5370	Cohn fraction V immunological test system
866.5520	Immunoglobulin G (Fab fragment specific) immunological test system
866.5530	Immunoglobulin G (Fc fragment specific) immunological test system
866.5540	Immunoglobulin G (Fd fragment specific) immunological test system
866.5700	Whole human plasma or serum immunological test system
866.5800	Seminal fluid (sperm) immunological test system
866.5860	Total spinal fluid immunological test system

## **PART 868 ANESTHESIOLOGY DEVICES**

868.1030	*	Manual algesimeter
868.1100		Arterial blood sampling kit
868.1575		Gas collection vessel
868.1870		Gas volume calibrator
868.1930		Stethoscope head
868.1965	*	Switching valve (ploss)
868.1975		Water vapor analyzer
868.2300		Bourdon gauge flowmeter
868.2320		Uncompensated thorpe tube flowmeter
868.2340		Compensated thorpe tube flowmeter
868.2350		Gas calibration flowmeter
868.2610		Gas pressure gauge
868.2620		Gas pressure calibrator
868.2700		Pressure regulator
868.2875		Differential pressure transducer
868.2885		Gas flow transducer
868.2900		Gas pressure transducer
868.5100		Nasopharyngeal airway
868.5110		Oropharyngeal airway
868.5220	*	Blow bottle
868.5240		Anesthesia breathing circuit
868.5280		Breathing tube support
868.5300		Carbon dioxide absorbent
868.5310		Carbon dioxide absorber
868.5320		Reservoir bag
868.5340		Nasal oxygen cannula
868.5350		Nasal oxygen catheter
868.5365		Posture chair for cardiac or pulmonary treatment
868.5375		Heat and moisture condenser (artificial nose)
868.5420	*	Ether hook
868.5460		Therapeutic humidifier for home use
868.5530		Flexible laryngoscope
868.5540		Rigid laryngoscope.
868.5550		Anesthetic gas mask
868.5560		Gas mask head strap
868.5570		Nonrebreathing mask
868.5580		Oxygen mask
868.5590		Scavenging mask
868.5600		Venturi mask
868.5760		Cuff spreader
868.5770		Tracheal tube fixation device
868.5780		Tube introduction forceps
868.5790		Tracheal tube stylet

868.5795	*	Tracheal tube cleaning brush
868.5810		Airway connector
868.5820		Dental protector
868.5860		Pressure tubing and accessories
868.5975		Ventilator tubing
868.5995		Tee drain (water trap)
868.6100		Anesthetic cabinet, table, or tray
868.6175	*	Cardiopulmonary emergency cart
868.6225	*	Nose clip
868.6400		Calibration gas
868.6700		Anesthesia stool
868.6820		Patient position support
868.6885		Medical gas yoke assembly

## **PART 870 CARDIOVASCULAR DEVICES**

870.1875	Stethoscope
870.2390	Phonocardiograph
870.2600	Signal isolation system
870.2620	Line isolation monitor
870.2640	Portable leakage current alarm
870.2810	Paper chart recorder
870.3650	Pacemaker polymeric mesh bag
870.3670	Pacemaker charger
870.3690	Pacemaker test magnet
870.3730	Pacemaker service tools
870.3935	Prosthetic heart valve holder
870.3945	Prosthetic heart valve sizer
870.4200	Cardiopulmonary bypass accessory equipment
870.4500	Cardiovascular surgical instruments

## **PART 872 DENTAL DEVICES**

872.1500	Gingival fluid measurer	
872.1730	Electrode gel for pulp testers	
872.1820	Dental x-ray exposure alignment device	
872.1840	Dental X-ray position indicating device	
872.1850	Lead-lined position indicator	
872.1905	*	Dental x-ray film holder
872.3080	Mercury and alloy dispenser	
872.3100	Dental amalgamator	
872.3110	Dental amalgam capsule	
872.3130	Preformed anchor	
872.3140	*	Resin applicator

872.3150 \* Articulator  
 872.3165 Precision attachment  
 872.3220 \* Facebow  
 872.3240 Dental bur  
 872.3285 Preformed clasp  
 872.3330 Preformed crown  
 872.3350 Gold or stainless steel cusp  
 872.3360 Preformed cusp  
 872.3410 Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive  
 872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive  
 872.3490 Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive  
 872.3520 OTC denture cleanser  
 872.3530 Mechanical denture cleaner  
 872.3580 Preformed gold denture tooth  
 872.3670 \* Resin impression tray material  
 872.3730 \* Pantograph  
 872.3830 Endodontic paper point  
 872.3840 Endodontic silver point  
 872.3850 Gutta percha  
 872.3900 Posterior artificial tooth with a metal insert  
 872.3910 Backing and facing for an artificial tooth  
 872.4130 Intraoral dental drill  
 872.4535 Dental diamond instrument  
 872.4565 Dental hand instrument  
     *510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.*  
 872.4620 Fiber optic dental light  
 872.4630 Dental operating light.  
 872.4730 Dental injecting needle  
 872.5410 Orthodontic appliance and accessories  
 872.5525 Preformed tooth positioner  
 872.5550 Teething ring **[510(k) exempt if the teething ring does not contain a fluid]**  
 872.6010 \* Abrasive device and accessories  
 872.6030 Oral cavity abrasive polishing agent  
 872.6050 \* Saliva absorber  
 872.6140 \* Articulation paper  
 872.6200 \* Base plate shellac  
 872.6250 Dental chair and accessories **(only chairs without operative unit device are 510(k) exempt)**  
 872.6290 \* Prophylaxis cup  
 872.6300 \* Rubber dam and accessories **(only accessories are 510(k) exempt)**  
 872.6390 Dental floss  
     *510(k) exempt only if the device is made of inert materials and is not coated or impregnated with chemicals intended to provide a therapeutic benefit or interact with tissues of the oral cavity.*

872.6475	Heat source for bleaching teeth
872.6510	Oral irrigation unit
872.6570 *	Impression tube
872.6640	Dental operative unit and accessories <b>(only the accessories tray to the unit is 510(k) exempt)</b>
872.6650 *	Massaging pick or tip for oral hygiene
872.6670 *	Silicate protector
872.6855 *	Manual toothbrush
872.6865	Powered toothbrush
872.6870 *	Disposable fluoride tray
872.6880 *	Preformed impression tray
872.6890 *	Intraoral dental wax

## **PART 874 EAR, NOSE, AND THROAT DEVICES**

874.1060	Acoustic chamber for audiometric testing
874.1080	Audiometer calibration set
874.1100	Earphone cushion for audiometric testing <i>510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.</i>
874.3375 *	Battery-powered artificial larynx
874.3540	Prosthesis modification instrument for ossicular replacement surgery <i>510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.</i>
874.4140	Ear, nose, and throat bur
874.4175	Nasopharyngeal catheter
874.4350	Ear, nose, and throat fiberoptic light source and carrier
874.4420	ENT manual surgical instrument <i>510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.</i>
874.4750	Laryngostroboscope
874.4770	Otoscope <i>510(k) exempt only when used in the external ear canal.</i>
874.5220 *	ENT drug administration device
874.5800	External nasal splint

## **PART 876 GASTROENTEROLOGY-UROLOGY DEVICES**

876.1075	Gastroenterology-urology biopsy instrument <i>Only biopsy forceps cover and the non-electric biopsy forceps are 510(k) exempt.</i>
876.1400	Stomach pH electrode.
876.1500	Endoscope and accessories <i>Only photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope are 510(k) exempt.</i>

876.1800	Urine flow or volume measuring system <i>Only disposable, nonelectrical urine flow rate measuring device, and nonelectrical urinometer are 510(k) exempt.</i>
876.4370	Gastroenterology-urology evacuator <i>Only the manually powered gastroenterology-urology evacuator is 510(k) exempt.</i>
876.4530	Gastroenterology-urology fiberoptic retractor
876.4560	Ribdam
876.4590	Interlocking urethral sound.
876.4730	Manual GU surgical instrument and accessories
876.4890	Urological table and accessories <i>Only the manually powered table (and accessories) and the stirrups for an electrically powered table are 510(k) exempt.</i>
876.5030	Continent ileostomy catheter
876.5090	Suprapubic urological catheter and accessories <i>Only the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar are 510(k) exempt.</i>
876.5130	Urological catheter and accessories <i>Only the ureteral stylet (guidewire), stylet for gastro-urological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder are 510(k) exempt.</i>
876.5450	Rectal dilator
876.5520	Urethral dilator <i>Only the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound are 510(k) exempt.</i>
876.5540	Blood access device and accessories <i>Only the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device are 510(k) exempt.</i>
876.5820	Hemodialysis system and accessories <i>Only accessories that are remote from the extracorporeal blood system and the dialysate delivery system, such as unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties are exempt from 510(k).</i>
876.5900	Ostomy pouch and accessories
876.5920 *	Protective garment for incontinence
876.5970 *	Hernia support

## **PART 878 GENERAL AND PLASTIC SURGERY DEVICES**

878.1800	Speculum and accessories
878.3250	External facial fracture fixation appliance <i>510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.</i>
878.3750	External prosthesis adhesive
878.3800 *	External aesthetic restoration prosthesis <i>This device is exempt from GMP regulation only if the device is intended for use without an external prosthesis adhesive to fasten it to the body.</i>
878.3900	Inflatable extremity splint



- 878.3910 \* Noninflatable extremity splint  
*510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.*
- 878.3925 Plastic surgery kit and accessories  
*510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.*
- 878.4100 Organ bag (**only the intestinal organ bag is 510(k) exempt**)
- 878.4160 Surgical camera and accessories
- 878.4380 Drape adhesive
- 878.4440 Eye pad
- 878.4450 Nonabsorbable gauze for internal use
- 878.4470 Surgeon's gloving cream
- 878.4635 Ultraviolet lamp for tanning
- 878.4660 Skin marker
- 878.4700 Surgical microscope and accessories
- 878.4730 Surgical skin degreaser or adhesive tape solvent
- 878.4800 Manual surgical instrument for general use
- 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.  
*Only special laser gas mixtures used as a lasing medium for this class of lasers are 510(k) exempt.*
- 878.4930 Suture retention device
- 878.4950 Manual operating table and accessories, and manual operating chair and accessories
- 878.5350 Needle-type epilator
- 878.5900 Nonpneumatic tourniquet
- 878.5910 Pneumatic tourniquet

## **PART 880 GENERAL HOSPITAL AND PERSONAL USE DEVICES**

- 880.2400 Bed-patient monitor
- 880.2700 \* Stand-on patient scale
- 880.2720 Patient scale
- 880.2740 \* Surgical sponge scale
- 880.2900 Clinical color change thermometer
- 880.5075 \* Elastic bandage
- 880.5110 Hydraulic adjustable hospital bed
- 880.5120 \* Manual adjustable hospital bed
- 880.5150 \* Nonpowered flotation therapy mattress
- 880.5160 \* Therapeutic medical binder
- 880.5180 Burn sheet
- 880.5210 Intravascular catheter securement device
- 880.5240 Medical adhesive tape and adhesive bandage
- 880.5300 \* Medical absorbent fiber
- 880.5510 Non-AC-powered patient lifts
- 880.5560 Temperature regulated water mattress
- 880.5630 Nipple shield

880.5640 \* Lamb feeding nipple  
 880.5740 Suction snakebite kit  
 880.5780 \* Medical support stocking  
     *Only stockings for general medical purposes are 510(k) and GMP.*  
 880.5820 \* Therapeutic scrotal support  
 880.5950 Umbilical occlusion device  
 880.6025 \* Absorbent tipped applicator  
 880.6050 \* Ice bag  
 880.6060 \* Medical disposable bedding  
 880.6070 \* Bed board  
 880.6080 \* Cardiopulmonary resuscitation board  
 880.6085 \* Hot/cold water bottle  
 880.6140 \* Medical chair and table  
 880.6150 Ultrasonic cleaner for medical instruments  
 880.6185 \* Cast cover  
 880.6190 \* Mattress cover for medical purposes  
 880.6200 \* Ring cutter  
 880.6230 \* Tongue depressor  
 880.6265 \* Examination gown  
 880.6280 Medical insole  
 880.6320 AC-powered medical examination light  
 880.6350 \* Battery-powered medical examination light  
 880.6430 \* Liquid medication dispenser  
 880.6450 \* Skin pressure protectors  
 880.6730 \* Body waste receptacle  
 880.6785 \* Manual patient transfer device  
 880.6800 \* Washers for body waste receptacles  
 880.6820 Medical disposable scissors  
 880.6900 \* Hand-carried stretcher  
 880.6960 \* Irrigating syringe  
 880.6970 Liquid crystal vein locator  
 880.6980 \* Vein stabilizer

## **PART 882 NEUROLOGICAL DEVICES**

882.1200 \* Two-point discriminator  
     *510(k) exempt only if the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976.*  
 882.1410 Electroencephalograph electrode/lead tester  
 882.1430 Electroencephalograph test signal generator  
 882.1500 \* Esthesiometer  
     *510(k) exempt only if the device is composed entirely of a single material.*  
 882.1525 \* Tuning fork  
 882.1700 \* Percussor

882.1750	Pinwheel
	<i>510(k) exempt only if the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976.</i>
882.1925	Ultrasonic scanner calibration test block
882.4030	Skull plate anvil
882.4125	Neurosurgical chair
882.4190	Clip forming/cutting instrument
882.4200	Clip removal instrument
882.4215	Clip rack
882.4325	Cranial drill handpiece (brace)
882.4440	Neurosurgical headrest
882.4500	Cranioplasty material forming instrument
882.4525	Microsurgical instrument
882.4535	Nonpowered neurosurgical instrument
882.4600	Leukotome
882.4650	Neurosurgical suture needle
	<i>510(k) exempt only if the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976.</i>
882.4900	Skullplate screwdriver

## PART 884 OBSTETRICAL AND GYNECOLOGICAL DEVICES

884.1550	Amniotic fluid sampler (amniocentesis tray)
	<b>New definition:</b>
	<i>The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocenteses tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at &lt;strong&gt;16&lt;/strong&gt;-18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity. [510(k) exempt]</i>
884.1640	Culdoscope and accessories
	<i>Only culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources are 510(K) exempt. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (non-inflatable) scissors, and suction/irrigation probe.</i>
884.1690	Hysteroscope and accessories
	<i>Only hysteroscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources are 510(k) exempt. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper, curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors.</i>

- 884.1700 Hysteroscopic insufflator  
*Only tubing and tubing/filter fits which only include accessory instruments which are not used to effect intrauterine access, e.g. hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation are 510(k) exempt.*
- 884.1720 Gynecologic laparoscope and accessories  
*Only gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources are 510(k) exempt. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe.*
- 884.1730 Laparoscopic insufflator  
*Only tubing and tubing/filter kits which include accessory instruments which are not used to effect intra-abdominal access, Verres needles etc.; and single-use tubing kits used for only intra-abdominal insufflation (pneumoperitoneum) are 510(k) exempt.*
- 884.2900 Fetal stethoscope
- 884.4520 OB-GYN general manual instrument
- 884.4530 Obstetric-gynecological specialized manual instrument  
*Only amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps are 510(k) exempt.*
- 884.5150 Nonpowered breast pump  
*510(k) exempt only if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.*
- 884.5900 Therapeutic vaginal douche apparatus.  
*510(k) exempt only if the device is operated by gravity feed.*
- 884.5920 Vaginal insufflator

## PART 886 OPHTHALMIC DEVICES

- 886.1040 Ocular esthesiometer
- 886.1050 Adaptometer (biophotometer)
- 886.1070 Anomaloscope
- 886.1090 Haidlinger brush
- 886.1140 \* Ophthalmic chair  
*The AC-powered device and manual devices are 510(k) exempt. The manual device is also exempt from GMP regulation.*
- 886.1150 \* Visual acuity chart
- 886.1160 Color vision plate illuminator
- 886.1170 \* Color vision tester
- 886.1190 \* Distometer
- 886.1200 \* Optokinetic drum
- 886.1250 Euthyscope (**only battery-powered is 510(k) exempt**)
- 886.1270 Exophthalmometer
- 886.1290 Fixation device

- 886.1320 \* Fornix scope
- 886.1330 \* Amsler grid
- 886.1340 Haploscope
- 886.1350 \* Keratoscope
  - The AC-powered device is exempt from 510(k) only when the device doesn't include computer software in the unit. The battery powered device is exempt from both 510(k) and GMP.*
- 886.1375 \* Bagolini lens
- 886.1380 \* Diagnostic condensing lens
- 886.1390 \* Flexible diagnostic Fresnel lens
- 886.1395 \* Diagnostic Hruby fundus lens
- 886.1400 \* Maddox lens
- 886.1405 Ophthalmic trial lens set
- 886.1410 \* Ophthalmic trial lens clip
- 886.1415 \* Ophthalmic trial lens frame
- 886.1420 Ophthalmic lens gauge
- 886.1425 Lens measuring instrument
- 886.1430 Ophthalmic contact lens radius measuring device
- 886.1435 Maxwell spot
- 886.1450 Corneal radius measuring device
  - 510(k) exempt only when the device doesn't include computer software in the unit or topographers.*
- 886.1460 \* Stereopsis measuring instrument
- 886.1500 \* Headband mirror
- 886.1605 \* Perimeter (**only manual device is 510(k) and GMP exempt**)
- 886.1650 \* Ophthalmic bar prism
- 886.1655 \* Ophthalmic Fresnel prism
- 886.1660 Gonioscopic prism
- 886.1665 \* Ophthalmic rotary prism
- 886.1680 Ophthalmic projector
- 886.1690 Pupillograph
- 886.1700 \* Pupillometer
  - The AC-powered device and manual devices are 510(k) exempt. The manual device is also exempt from GMP regulation.*
- 886.1750 Skiascopic rack
- 886.1760 Ophthalmic refractometer
- 886.1770 \* Manual refractor
- 886.1790 \* Nearpoint ruler
- 886.1800 Schirmer strip
  - 510(k) exempt only if the device is made of the same materials that were used in the device before May 28, 1976.*
- 886.1810 \* Tangent screen (campimeter)
  - The AC-powered and battery-powered devices are 510(k) exempt. The battery-powered device is also exempt from GMP.*
- 886.1840 \* Simulatan (including cross cylinder)

- 886.1860 \* Ophthalmic instrument stand  
*The AC-powered and battery-powered devices are 510(k) exempt. The battery-powered device is also exempt from GMP.*
- 886.1870 \* Stereoscope  
*The AC-powered and battery-powered devices are 510(k) exempt. The battery-powered device is also exempt from GMP.*
- 886.1880 \* Fusion and stereoscopic target
- 886.1905 \* Nystagmus tape
- 886.1910 \* Spectacle dissociation test system  
*The AC-powered and battery-powered devices are 510(k) exempt. The battery-powered device is also exempt from GMP.*
- 886.1945 Transilluminator **(only battery-powered is 510(k) exempt)**
- 886.3200 Artificial eye  
**New Definition:**  
*An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.*  
  
*510(k) exempt only if the device is made from the same materials, has the same chemical composition, and uses the same manufacturing processes as currently legally marketed devices.*
- 886.4230 \* Ophthalmic knife test drum
- 886.4250 Ophthalmic electrolysis unit **(only battery-powered is 510(k) exempt)**
- 886.4335 \* Operating headlamp **(only battery-powered is 510(k) exempt)**
- 886.4350 Manual ophthalmic surgical instrument
- 886.4360 Ocular surgery irrigation device
- 886.4445 \* Permanent magnet
- 886.4570 Ophthalmic surgical marker
- 886.4750 \* Ophthalmic eye shield
- 886.4770 \* Ophthalmic operating spectacles (loupes)
- 886.4855 \* Ophthalmic instrument table  
*The AC-powered device and manual devices are 510(k) exempt. The manual device is also exempt from GMP regulation.*
- 886.5120 \* Low-power binocular loupe
- 886.5420 Contact lens inserter/remover
- 886.5540 \* Low-vision magnifier
- 886.5600 \* Ptosis crutch
- 886.5800 \* Ophthalmic bar reader
- 886.5810 \* Ophthalmic prism reader
- 886.5820 Closed-circuit television reading system **(only AC-powered device)**
- 886.5840 \* Magnifying spectacles
- 886.5842 Spectacle frame
- 886.5844 Prescription spectacle lens
- 886.5870 \* Low-vision telescope
- 886.5900 Electronic vision aid
- 886.5910 \* Image intensification vision aid

886.5915 \* Optical vision aid

*The AC-powered and battery-powered devices are 510(k) exempt. The battery-powered device is also exempt from GMP.*

## **PART 888 ORTHOPEDIC DEVICES**

888.1100 Arthroscope

*Only the following manual arthroscopic instruments: cannulas, currettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knotpushers, suture punches, switching rods, and trocars, are 510(k) exempt.*

888.1250 Nonpowered dynamometer

888.1520 Nonpowered goniometer

888.3000 Bone cap

888.4150 Calipers for clinical use

888.4200 Cement dispenser

888.4210 Cement mixer for clinical use

888.4220 Cement monomer vapor evacuator

888.4230 Cement ventilation tube

888.4300 Depth gauge for clinical use

888.4540 Orthopedic manual surgical instrument

888.4600 Protractor for clinical use

888.4800 Template for clinical use

888.5850 \* Nonpowered orthopedic traction apparatus and accessories

888.5890 \* Noninvasive traction component

888.5940 \* Cast component

888.5960 Cast removal instrument

888.5980 \* Manual cast application and removal instrument

## **PART 890 PHYSICAL MEDICINE DEVICES**

890.1175 \* Electrode cable

890.1575 Force-measuring platform

890.1600 Intermittent pressure measurement system

890.1615 Miniature pressure transducer

890.3025 \* Prosthetic and orthotic accessory

890.3075 \* Cane

890.3100 Mechanical chair

890.3150 \* Crutch

890.3175 Flotation cushion

890.3410 \* External limb orthotic component

890.3420 \* External limb prosthetic component

890.3475 \* Limb orthosis

890.3490 \* Truncal orthosis

890.3520 \* Plinth

890.3640	*	Arm sling
890.3665	*	Congenital hip dislocation abduction splint
890.3675	*	Denis Brown splint
890.3700	*	Nonpowered communication system
890.3750		Mechanical table
890.3760		Powered table
890.3790	*	Cane, crutch and walker tips and pads
890.3825	*	Mechanical walker
890.3910	*	Wheelchair accessory
		<i>510(k) exempt as long as the device is not labeled or otherwise represented as a protective restraint.</i>
890.3920		Wheelchair component
890.3940	*	Wheelchair platform scale
890.5050	*	Daily activity assist device
890.5125	*	Nonpowered sitz bath
890.5350	*	Exercise component
890.5370	*	Nonmeasuring exercise equipment
890.5380		Powered exercise equipment
890.5410		Powered finger exerciser
890.5660		Therapeutic massager
890.5700	*	Cold pack
890.5730	*	Moist heat pack
890.5765		Pressure-applying device
890.5925	*	Traction accessory
890.5940		Chilling unit
890.5950		Powered heating unit
890.5975		Therapeutic vibrator

## **PART 892 RADIOLOGY DEVICES**

892.1130		Nuclear whole body counter
892.1350		Nuclear scanning bed <b>(with limitations)</b>
		<i>510(k) exempt only when the device is labeled with weight limit, is used with planar scanning only, and is not for diagnostic x-ray use.</i>
892.1370		Nuclear anthropomorphic phantom
892.1380		Nuclear flood source phantom
892.1400		Nuclear sealed calibration source
892.1420		Radionuclide test pattern phantom
892.1640		Radiographic film marking system
892.1700		Diagnostic X-ray high voltage generator
892.1760		Diagnostic X-ray tube housing assembly
892.1770		Diagnostic X-ray tube mount
892.1830		Radiologic patient cradle
892.1840		Radiographic film
892.1880		Wall-mounted radiographic cassette holder



892.1920 \* Radiographic head holder  
892.1940 \* Radiologic quality assurance instrument  
892.1950 \* Radiographic anthropomorphic phantom  
892.5740 Radionuclide teletherapy source  
892.5780 Light beam patient position indicator *(for diagnostic purposes only, not therapeutic - the Federal Register and CFR make no distinction and are in error))*  
892.6500 Personnel protective shield  
*510(k) exempt only if the device's labeling specifies the lead equivalence.*